AZISOFT

(Azithromycin U.S.P.)

ایزیسوفٹ

(ایزیتھرومائسن یو۔ایس۔پی۔)

Compositions:
Each capsule contains:
Azithromycin dihydrate (U.S.P.)
equivalent to azithromycin 250mg

Each film-coated tablet contains:
Azithromycin dihydrate (U.S.P.)
equivalent to azithromycin 500mg

Each 5ml oral suspension contains:
Azithromycin dihydrate (U.S.P.)
equivalent to azithromycin.....200mg

Properties:
Azithromycin is an azalide, derived from the macrolide class of antibiotics. Azithromycin demonstrates activity in vitro, against a wide range of Gram-positive and Gram-negative bacteria including staphylococcus aureus, Streptococccus pneumoniae, Streptococcus pyogenes (Group A) and other Streptococcal species; Haemophilus influenzae and para-influenzae; Moraxella catarrhalis; anaerobes including Bacteroids fragilis; Escherichia coli; Bordetella pertussis; Bordetella parapertussis; Borrelia burgdorferi; Haemophilus ducreyi; Neisseria gonorrhoeae and Chlamydia trachomatis. Azithromycin also demonstrates in-vitro activity against Legionella pneumophila, Mycoplasma pneumoniae and hominis, Campylobacter sp, Toxoplasma gondii and Treponema pallidum.

Pharmacokinetics:
Following oral administration in humans, azithromycin is widely distributed throughout the body; bioavailability is approximately 37%. The time taken to reach peak plasma levels is 2-3 hours. Plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. Kinetic studies have shown markedly higher azithromycin levels in tissue than in plasma (upto 50 times the maximum observed concentration in plasma) indicating that the drug is highly tissue bound. Concentrations in target tissue such as lungs, tonsils and prostate exceed the MIC90 for likely pathogens after a single dose of 500mg.

Indications:
Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in upper respiratory tract infections including otitis media, pharyngitis/tonsillitis and sinusitis, skin and soft tissue infections and acne, mild to moderate typhoid fever caused by multi-drug resistant strains.
In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis.
Azithromycin is indicated as second line therapy for typhoid fever caused by s. typhi and s.paratyphi.

Dosage and administration:
Azithromycin should be administered as single dose, and as common with many other antibiotics, should be taken at least 1 hour before or 2 hours after food.

Adults:
For respiratory tract infections and skin and soft tissue infections the total dose is 1.5g which should be given as 500mg as a single dose daily for 3 days. Alternatively an initial dose of 500mg in the first day may be followed by 250mg daily for further 4 days.

For sexually transmitted disease caused by Chlamydia trachomatis the dose is 1g given as a single dose. For typhoid fever; the dose is 500mg to 1000mg once daily for 5-7 days.

Use in children:
There is no information on children under six months of age. The dose in children is 10mg/kg as a single daily dose for 3 days. For typhoid fever therapy should be given for 7 days.

AGE (YRS)	WEIGHT (KG)	DOSAGE (10MG/KG)
0.5-2.0	4.5-12.0	1.5-3.0ml (45-120mg)
2.5-4.0	14.0-16.0	3.5 - 4.0ml (140-160mg)
4.5-6.0	17.0-20.5	4.5 - 5.0ml (170-205mg)
6.5-8.0	21.5-25.0	5.0 - 6.5ml (215-250mg)
8.5-10.0	26.5-31.0	6.5 - 8.0ml (265-310mg)
10.5-12.0	33.0-40.0	8.5 - 10.5ml (330-400mg)
12.5-14.0	41.0-50.5	11.0 - 12.5ml (410-505mg)
14.5-16.0	52.0-62.0	13.5 - 15.5ml (520 - 620mg)
16.5-18.0	64.0-69.0	16.0 - 17.0ml (640-690mg)

Contra-Indications:
Azithromycin is contra-indicated in patients with a known hypersensitivity to azithromycin or any macrolide antibiotics.

Precautions and warnings:
As with any antibiotic, observation for signs of superinfection with non susceptible organisms, including fungi is recommended. As with erythromycin and other macrolides, serious allergic reactions, including angioneurotic oedema and anaphylaxis, have been reported. Some of these reactions with azithromycin have resulted in recurrent symptoms and required a long period of observation and treatment.

Use in renal impairment:
No dosage adjustment is needed in patients with mild renal impairement (Creatinine Clearance > 40ml/min.) but there are no data regarding azithromycin usage in patients with more severe renal impairment, thus caution should be exercised in using azithromycin in these patients.

Use in hepatic impairment:
As liver is the principal route of excretion of azithromycin, it should not be used in patients with hepatic disease.

Use during pregnancy and lactation
Use in pregnancy:
Animal reproduction studies have demonstrated that azithromycin crosses the placenta, but have revealed no evidence of harm to the foetus. There are no adequate and well controlled studies in pregnant women. Since animal reproduction studies in pregnant women. Since animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if adequate alternatives are not available.

Use in lactation:
No data on secretion of azithromycin in breast milk are available, so azithromycin should only be used in lactating women where adequate alternatives are not available.

Drug interactions:

Antacids:
In patients receiving azithromycin and antacids, azithromycin should be taken at least 1 hour before or 2 hours after the antacid.

Carbamazepine:
In a pharmacokinetics interaction study in healthy volunteers, no significant effect was observed on the plasma levels of carbamazepine or its active metabolite.

Cyclosporin:
Some of the related macrolide antibiotics interfere with the metabolism of cyclosporin. In the absence of pharmacokinetics studies or clinical data investigating potential interaction between azithromycin and cyclosporin, caution should be exercised before co-administration of these two drugs. If co-administration is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly.

Digoxin:
No interactions have been reported in patients who have received concomitant azithromycin and cardiac glycosides. However, some of the macrolide antibiotics have been reported to impair the metabolism of digoxin (in the gout) in some patients.
Therefore, in patients receiving concomitant azithromycin and digoxin the possibility of raised digoxin levels should be borne in mind.

Ergot derivatives:
Because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administered.
Warfarin:
In a pharmacokinetics interaction study, azithromycin did not alter the anticoagulant effect of a single 15mg dose of warfarin administered in healthy volunteers. Azithromycin and warfarin may be co-administered, but monitoring of the prothrombin time should be continued as routinely performed.

Side-effects:
Azithromycin is well tolerated with a low incidence of side effects. Most side-effects observed were mild to moderate in severity. The majority of side-effects were of gastrointestinal origin with nausea, abdominal discomfort (pain/cramps), vomiting, flatulence, diarrhoea and loose stools being occassionally observed. Allergic reactions such as rashes have occured and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have been seen with a frequency similar to the comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a casual relationship to azithromycin has not been established.

Overdosage:
There are no data on overdosage with azithromycin.
Typical symptoms of overdosage with macrolide antibiotics, include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

Instructions:
Store at room temperature (15-25°C). Protect from moisture and sunlight. Keep all medicines out of the reach of childrens. To be sold on the prescription of a registered medical practitioner only.

Pack size:
Capsules:
250mg, 10's capsules in blister pack.

Tablets:
500mg, 6's tablets in blister pack.

Suspension:
200mg/5ml, granules for 15ml oral suspension.

ہدایات :
دوا کو (15 – 25°C) درجہ حرارت پر نمی اور دھوپ سے محفوظ رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ دوا صرف مستند ڈاکٹر کے
نسخہ پر ہی فروخت کی جائے۔

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